



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Morris Samelson and Johnathan M. Scharff	ATTY DKT NO.: P-5435(DIV2)
SERIAL NO.: 10/601,795	GROUP ART UNIT: 1615
FILED: June 23, 2003	EXAMINER: Lakshmi Sarada
TITLE: Ultra Fine Dead Sea Mineral Compound and Method of Manufacture	Channavajjala

TO: **Commissioner of Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

DECLARATION UNDER 37 C.F.R. § 1.132

Dear Examiner Channavajjala:

I, Terrance C. Clifford, declare as follows:

1. I am a Pharmaceutical Production Manager by trade.
2. I hold Bachelor of Science degrees in Chemical Engineering, Pharmacy and Psychology. I have twenty-three years experience in the pharmaceutical field, including work as a practicing pharmacist and as Manager in compounding pharmaceutical products. I possess knowledge in the production and control of tablets, capsules, emulsions, suspensions, ointments, and sterile liquid dosage forms. I am a Registered Pharmacist in the state of Texas.
3. I was requested by the inventor of the present invention to perform an independent study to attempt to formulate a product having the consistency of a cream or thick lotion with good emollient characteristics incorporating the maximum amount of Dead Sea salts without affecting the stability of the lotion. In order to achieve a product with good emollient characteristics and absence of a greasy feel, an oil-in-water emulsion was chosen as the basis for the formulation.
4. Emulsions are inherently unstable in the presence of salts. Sodium chloride concentrations as low as 0.1% can adversely affect viscosity and stability of the emulsion. As a result, I conducted a literature search to find emulsifiers that would be stable in the presence of salts. Brij 721 and Brij 72 were chosen as emulsifiers in order to incorporate the maximum amount of Dead Sea salt because they were readily available, seemed to tolerate moderate salt levels, and appeared to form emulsions that were not too greasy.

5. Several formulations were prepared in the laboratory using varying levels of emulsifiers and salt concentrations. More specifically, I worked to incorporate various levels of Brij 721, between 1 and 10% with 8.21% being the optimal and final amount included in the formulation. Furthermore, I worked to incorporate various levels of Brij 72, between 1 and 10% with 3.25% being the optimal and final amount included in the formulation. As expected I found that increased levels of emulsifiers permitted higher levels of Dead Sea salts to be incorporated. I worked with various levels of salts between 1 and 10% in the preparations. However the higher levels of emulsifiers created formulations that were far too greasy and would not be desirable by a typical consumer.

6. Eventually emulsifier levels were chosen that incorporated Dead Sea salt levels of a maximum of 4%. In order to optimize the formulation for tactile properties, I added octyl palmitate, dimeticone, glyceryl stearate, dehymuls PGPH, glycerin, and cetyl alcohol. Chemical and microbial stability were enhanced by the addition of covitol 1250, Vitamin A palmitate, and diazolidinyl urea. The final formulation passed several freeze thaw cycles to demonstrate emulsion stability.

7. As shown from these experiments, a significant difference in formulation was obtained by preparing an aqueous emulsion. Due to the instability of the oil-in-water emulsion, no more than 5% total weight of the composition of Dead Sea salt could be incorporated without causing a detrimental effect on the "feel" of the composition.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

6/23/05  
Date

Terrance C. Clifford  
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